## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE REFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Anthony E. BOLTON et al.

Title: INFLAMMATORY CYTOKINE

SECRETION INHIBITION

Appl. No.: 10/002,634

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Art Unit: 1644

Confirmation 1971

Number:

## Summary of Claimed Subject Matter under 37 CFR 41.37(c)(1)(v)

Mail Stop Appeal Brief - Patents P.O. Box 1450 Alexandria VA 22313-1450

Sir:

Under the provisions of 37 C.F.R. § 41.37(e)(1)(v) and pursuant to MPEP 1205.03 (B), this paper on Summary of Claimed Subject Matter is being filed with in one month or thirty days from the mailing date of the Notification of Non-compliant Appeal Brief under 37 C.F.R. 41.37, dated 17 May 2007. Since this paper on Summary of Claimed Subject Matter is being filed on or before 18 June 2007, (the 17<sup>th</sup> being Sunday) no extension fee is required to enter this paper. An authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned Deposit Account No. 19-0741.

Please amend the Summary of Claimed Subject Matter in the Appeal Brief filed on 26 March 2007 as follows:

## SUMMARY OF CLAIMED SUBJECT MATTER

The invention is drawn to a method of decreasing the expression of one or more of the inflammatory cytokines IFN-y and IL-6 by cells in a mammalian patient using extracorporeally (i.e., ex vivo) stressed autologous blood.

In particular, the invention is drawn to a method of decreasing expression of one or more inflammatory cytokines, selected from the group of IFN- $\gamma$  and IL-6, in a mammalian patient, said method comprising:

selecting a patient with an excess of inflammatory cytokines, selected from the group of IFN- $\gamma$  and IL-6;

withdrawing an aliquot of blood comprising blood cells from said patient;

subjecting said blood cells extracorporeally to stress comprising both an oxidative condition and an ultraviolet stressor simultaneously;

administering to said patient an effective amount of stressed mammalian blood cells, wherein the expression of one or more inflammatory cytokines in said patient is decreased.

See, e.g., page 2, lines 14-18, page 3, lines 1-6, and Figures 1 and 2.

The invention is also drawn to medical treatment of patients suffering from, prone to, or at risk of contracting, a disorder associated with excessive amounts of one or more of the inflammatory cytokines IFN-y and IL-6.

In particular, the invention is drawn to a method for the treatment or prophylaxis of chronic fatigue syndrome in a mammalian patient characterized by an excessive level of, or excessive sensitivity to, IL-6 cytokines in said patient, which method comprises:

selecting a patient suffering from or at risk of suffering from chronic fatigue syndrome; withdrawing an aliquot of blood comprising blood cells from said patient;

subjecting said blood cells extracorporeally to stress comprising both oxidative conditions and ultraviolet conditions simultaneously;

administering to said patient an effective amount of stressed mammalian blood cells, wherein the level of IL-6 cytokines in said patient is reduced.

See, e.g., page 2, lines 22-26. Such disorders associated with excessive amounts of IFN- $\gamma$  and/or IL-6 include contact hypersensitivity (CHS). See page 2, lines 25-28. Example 1 describes the treatment of CHS in mice according to the methods of the invention. Page 10, et seq.

The blood is stressed extracorporeally by application of two stressors, oxidative conditions and ultraviolet conditions simultaneously (page 4, lines 24-28). The application provides details for stressing the autologous blood using an oxidizing environment (page 5, line 28 to page 6, line 20), and/or ultraviolet radiation (page 6, line 21 to page 7, line 11), and optionally, using the additional stressor of thermal conditions (page 5, lines 7-27). Such conditions are also described in the Example, in the context of treating CHS in mice.

The identification of a mammalian patient manifesting an excess of inflammatory cytokines, IFN- $\gamma$  and/or IL-6 is disclosed in the application, for example, at page 3, lines 21-22, at page 8, lines 24-28 and at page 9, line 20 to page 10, line 3.

Reconsideration of this paper on Summary of Claimed Subject Matter is respectfully requested.

Respectfully submitted,

Date 18 June 2007

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